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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 046714/0113

In re: U.S. Patent No. 5,362,755

Patentee: Timothy J. BARBERICH, *et al.*

Assignee: Sepracor, Inc.

Issue Date: November 8, 1994

COMMUNICATION

Commissioner of Patents and Trademarks
Washington, D.C. 20231
BOX PATENT EXT.

Sir:

In response to the FDA's June 23, 2004 letter in the above-captioned patent term extension application, the patentee wishes to clarify one statement in the FDA's letter. This does not affect the term of extension being sought, but is merely provided as a clarification of the record for the PTO. In numbered paragraph 1, FDA states that "[t]he applicant claims February 28, 1995 as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 30, 1995, which was thirty days after FDA receipt of the IND."

To the contrary, patentee's original patent term extension application states that the IND became effective on the same date (March 30, 1995) identified by the FDA (see page 9 of originally filed application for extension). Moreover, patentee's calculation of patent term (page 12 of originally filed application for extension) correctly uses the March 30, 1995 date

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as the date for calculating an extension.

Accordingly, patentee wishes to clarify the record by pointing out this information to the Patent Office.

Respectfully submitted,

Aug. 4, 2004
Date


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